3.0 Summary of Safety and Effectiveness Information

APR 1 8 2003

SYNTHES (U.S.A.)
1380 Enterprise Drive
West Chester, PA 19380

(610) 647-9700
Contact: Jonathan Gilbert
3/18/02

DEVICE: Synthes Spine Anterior CSLP System [formerly known as: Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System (as part of Synthes Anterior Cervical Vertebrae Plate System, K945700),10/27/97]

DESCRIPTION
The Synthes Anterior Cervical Vertebrae Plate System including the Small Stature Anterior Cervical Vertebrae Plate System consists of plates with expansionhead screws and locking screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). The implants of these systems are manufactured from titanium.

INDICATIONS
The Synthes Anterior CSLP System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications:

1. Spondylolisthesis
2. Fracture
3. Spinal stenosis
4. Tumor
5. **Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).**

CLASSIFICATION:
The classification of the subject device is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3060: Spinal intervertebral body fixation orthosis. The product code is KWQ. The Panel code is 87.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The components of the Synthes Spine Anterior CSLP system are the equivalent to components of previously cleared spinal systems. Information on the performance of the subject device compared to the performance of previously cleared spinal systems with similar indications has been provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2003

Mr. Jonathan Gilbert
Project Manager, Regulatory Affairs
SYNTHES Spine
1380 Enterprise Drive
West Chester, Pennsylvania 19380

Re: K030866
Trade Name: Synthes Anterior CSLP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 18, 2003
Received: March 19, 2003

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

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510(k) Number (if known): NA

Device Name: **Synthes Anterior CSLP System**

INDICATIONS
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030866